DEPARTMENT OF HEALTH & HUMAN SERVICES   PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

March 13, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeffrey W. Jones
President
HGM Medical Laser
3959 West 1820 South
Salt Lake City, Utah 84104

PURGED

Ref. # - DEN-97-13

Dear Mr. Jones:

During an inspection of HGM Medical Laser conducted between February 3 and 6, 1997, Consumer Safety Officer Martina E. Ctrnacty determined that your firm manufactures medical lasers. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to conduct all processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). For example, several Design Change Notices (DCNs) were released to production prior to final sign-off as required by your SOP.

2. Failure to completely investigate the failure of a device or any components to meet performance specifications after the device has been released for distribution, as required by 21 CFR 820.162. For example, there was no documentation of failure analysis or failure investigation for the following complaints: , received 1/3/96; received 11/10/95; , received 7/28/96 and , received 4/20/95.

3. Failure to communicate approved changes in the manufacturing process to appropriate personnel in a timely manner, as required by 21 CFR 820.100(b)(3). For example, Regular Change Notice dated 6/13/96 was released on 9/10/96, however, the current has not been updated to reflect the current procedure.

4. Failure to routinely calibrate, inspect, and check all production and quality assurance measurement equipment as required by 21 CFR 820.61. For example, the was due for calibration in January 1997. Our inspection revealed this equipment was in use on February 5, 1997 on the production/QA floor without being calibrated.

5. Failure to perform maintenance of equipment necessary to assure the manufacturing specifications are met, as required by 21 CFR 820.60(a). For example, there was no documentation that the has had preventative maintenance as required by the Operator's Manual.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for products manufactured at your Denver facility, we are requesting that you submit to this office, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device GMP regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by you that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The certifications of audit and corrections should be submitted to this office by October 1, 1997.

We are in receipt of your February 19, 1997, response to the FDA-483. Although your response promises corrective action to all the issues indicated, similar issues were noted during the 1994 and 1995 inspections of your firm. We note that at the conclusion of both these inspections, your firm also promised corrective actions, however deviations continue to occur.

Please notify this office when the facility will be ready for inspection. Until the adequacy of the corrections can be confirmed, clearance of the premarket submissions noted above will be withheld.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: Regina A. Barrell, Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

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